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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

NOTIFICATION DATE	DELIVERY MODE
10/30/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	09/423,042	GUY ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-9,11,14,15,18,25,37-40 and 42-47* is/are pending in the application.

4a) Of the above claim(s) *11,43 and 44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-9,14,15,18,25,37-40,42 and 45-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 11 and 43-44 stand withdrawn from consideration.
Claims 5-9, 14-15, 18, 25, 37-40, 42, and 45-47 are under consideration.
Claims 1-4, 10, 12-13, 16-17, 19-24,26-36 and 41 have been canceled.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections/Rejections Withdrawn

1. Claim 5 rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al (1993) in light of Applicant's definition of an Helicobacter pylori antigen at page 11 which includes polypeptides that are similar to a Helicobacter pylori polypeptide antigen and is able to induce an immune response against Helicobacter (see page 11, lines 19-23) is herein withdrawn in light of Applicant's traversal and claim amendments.

Rejections Maintained/Response to Arguments

2. Applicant's arguments filed August 14, 2007 have been fully considered but they are not persuasive.

3. The scope of enablement rejection over claims 25,37-40,42,45-47 under 35 U.S.C. 112, first paragraph (scope of enablement and written description) is traversed by stating that "the claims have been amended to specify that which the Examiner has deemed to be enabled: the use of prophylactically effective H. pylori polypeptide antigens in methods of inducing a prophylactic immune response, using the specific regimens and routes specified in the claims.".

4. It is the position of the examiner that claim 42 still recites the term antigen, peptide and DNA and depends from independent claim 25, therefore the scope of claim 25 encompasses antigens, peptides and DNA molecule despite the fact that claim 25 has been amended to recite the phrase "polypeptide antigen. Claims 25, 37-40, 42, 45-47 are still rejected based upon the scope of enablement for reasons of record. The lack of written description is maintain over

claim 25 and dependent claims therefore in light of claim 42 depending from claim 25 which defines the scope of claim 25 to include antigens, peptides and DNA molecules of any species or sequence, for reasons of record, and in light of the fact that Applicant's traversal is not commensurate in scope with the instant claimed invention.

5. The rejection of claims 5-6, 14-15, 18, 25, 37, 38,39-40, 42 and 47 under 35 U.S.C. 102(b) as being anticipated by WO96/31235 in light of the English version US Patent No 6,126,938, is traversed on the grounds that claims 5, 6, 10, 12, 14-15 and 18 recite the phrase "consists essentially of subdiaphragmatic, systemic administration thus excluding additional administration routes.

6. It is the position of the examiner that the phrase "consists essentially of" is open language permitting additional method steps as long as they do not change the basic and novel characteristic of the instantly claimed method, the instant method being directed to a method of inducing a prophylactically effective immune response against Helicobacter pylori. In light of the fact that WO96/31235 is directed to stimulating an immune response against Helicobacter pylori, and administers compositions (by a mucosal route in addition to the dorsolumbar route,) which doe not change the basic and novel characteristic of the claimed methods, WO96' still anticipates the claimed invention.

7. Applicant additionally traverses the application of WO96/31235 on the basis that the instant claims specify that the first administration to the patient is by mucosal administration to prime and the second administration is to boost the immune response.

8. It is the position of the examiner that WO96/31235 administers a mucosal prime and a parental boost, wherein the reference primes both a parental and mucosal routes and boosts both parenteral and mucosal routes. WO96/31235 still anticipates the instantly claimed invention as now claimed.

9. It is the position of the examiner that Applicant claims the administration of the Helicobacter pylori polypeptide to the dorsolumbar region (pending claim 18, depends from claim 5) and therefore has not excluded this embodiment from the scope of the claims and actually has included this embodiment within the scope of what is now claimed.

10. With respect to the recitation of the phrase "comprising in order the steps of:" mucosally administering... then parenterally administering, it is the position of the examiner that WO96/31235 discloses carrying out these steps more then one time (see English translation US Pat. 6,126,938, col. 7, lines 1-2), wherein the method would comprise mucosal followed by parenteral, even if an additional step of parenteral was carried out before the mucosal step (see instant claims 37 and 38). Clearly the WO96/31235 document discloses a method that comprises repeat repeating the parenteral administration (first agent) followed by the second agent (mucosal) repeated first agent (parenteral) repeated second agent (mucosal). Therefore the method of WO96/32135 does disclose the method step of mucosal followed by parenteral in that order.

11. With respect to oral administration, WO96' English translation, states that the mucosal immune response can be obtained by the oral route (see '938, col. 2, line 36; col. 6, line 21 "oral route" and '938, claim 6). The instantly claimed method has not been distinguished from the

method of Guy et al that repeats the administration of the (prime/boost) parenteral/mucosal/ parenteral/mucosal and therefore comprises a method that is mucosal before parenteral.

12. Guy et al discloses a method that administers the Helicobacter pylori polypeptides by the vaginal or rectal route (see '938, col. 6, line 27) which is a subdiaphragmatic, systemic route, as well as administers the Helicobacter pylori polypeptide by systemic injection at the dorsolumbar region by intramuscular injection (instant claim 18).

> Additionally, the mucosal immune responses were measured based upon systemic, circulating antibodies present in serum:
> "On days 14, 35 and 56, serum samples are drawn from each of the mice. The production of anti-urease antibodies is tested for by ELISA (a purified soluble extract of H. pylori is used).
>
> 141
>
> The results summarized in FIG. 9 show that the various immunization protocols enable a strong IgG response and a smaller IgA response to be induced."

Administering a composition mucosal will induce both a local mucosal immune response, and in light of the disclose of WO96', a systemic immune response as well. The reference still anticipates the instantly claimed invention as now claimed. Prior responses are incorporated herein by reference.

1. ***Obviousness-type Double Patenting*** The rejection of claims 5-9, 14-15, 25, 39-40,42, 45-47 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,126,938 (common inventor Bruno Guy) is traversed on the grounds that independent claim 1 of '938 requires multiples administration steps.
2. It is the position of the examiner that the instant claims do not exclude from the scope of the claims methods that have multiple steps of administration as long as the method does not change the basic and novel characteristic of the instantly claimed method. A single step method is directed to a genus of methods that comprise this step. The allowed method is a species of method that is within a genus method that comprises a single step method, the single step method and the multiple step method comprising the same step as the single step method.

13. Applicant additionally traverses the application of 6,126,938 on the basis that the instant claims specify that the first administration to the patient is by mucosal administration to prime and the second administration is to boost the immune response.

14. It is the position of the examiner that 6,126,938 administers a mucosal prime and a parental boost, wherein the reference primes both a parental and mucosal routes and boosts both

parenteral and mucosal routes. 6,126,938 still anticipates the instantly claimed invention as now claimed. . Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed methods are directed to a species of the instantly claimed genus of methods that administer by the sub-diaphragmatic, systemic route, and the allowed method claims include the methods step of urogenital administration (see allowed claim 5) or intragastric administration (see allowed claim 9) and the first product is formulated and parenterally administered, by subcutaneous, intradermal or intramuscular administration and the location of the parenteral administration is (see allowed claims 27-28) defined to include dorsolumbar region for injection (see US Pat. 6,126,938, col. 5, lines 8-17). The allowed species anticipates the instantly claimed genus of methods as now claimed.

15. Additionally, US Pat. 6,126,938, also discloses a method that comprises the steps of mucosally administering a Helicobacter pylori antigen (see allowed claims 10-11), which is by an oral or intragastric mucosal route (see allowed claims 15 and 18), and parenterally administering Helicobacter pylori antigen (see allowed claims 7-8, and 27-28 and col. 8, line 19). The antigens are encoded by a DNA in an expression cassette (see allowed claims 3 and 26) and are in association with a non-toxic adjuvant, the adjuvant being defined to a "lipid mixture of cholesterol, dipalmitoylphosphatidyl-choline (see allowed claim 20 and col. 11, lines 54-58). This allowed species of invention anticipates the instantly claimed genus of methods that comprise first and second steps of mucosally and parenterally administering Helicobacter pylori antigen to a mammal.

16. The rejection of claim 5-8 and 18 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,576,244 (common inventors with instant Application: Weltzin and Bruno Guy) is traversed on the grounds that the '244 patent does not mention administration by "subdiaphragmatic, systemic routes" as required by the claims.

17. It is the position of the examiner that Applicant defines the systemic route to include "the subcutaneous route, the intramuscular route and the intradermal route (see instant claim 18)". US Pat. 6,576,244 administers a composition by a subcutaneous (allowed claim 5) or intradermal route(allowed claim 6), the subcutaneous route being defined to be the lower back (see col. 9, lines 8-14) and the intradermal route being defined to include skin of the back (see '244, col. 9, lines 14-19). The allowed species anticipates the instantly claimed genus of methods as now claimed.

18. The rejection of claim 5 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, (UreA and UreB are defined to be Helicobacter pylori antigens (see Spec. col. 11, lines 62-63), 13 (mucosal: defined to include anal, vaginal and intragastric , col. 14, lines 19-20), 15 (Intragastrically) and 18 (prophylactic) of U.S. Patent No. 6,379,675, is traversed on the grounds that '675 requires the administration of OSP antigens which are B. burgdorferi lipoproteins in contrast to the H.pylori antigens of the present claims.

19. It is the position of the examiner that the methods of '675 administer Helicobacter pylori antigen by a sub-diaphragmatic, systemic route, wherein the method of US 6,379,675, is able to induce strong circulatory immune responses of IgG and IgA in the serum (see col. 13 ,lines 25-26)

directed to Helicobacter pylori UreA and UrB antigens. While it is true that method administers a composition that includes an OspA antigen and an adjuvant, the allowed method also administers Helicobacter pylori polypeptide antigen (allowed claim 1 "UreA" and "UreB". The allowed method is a species encompassed by the instantly claimed genus of methods that administer any Helicobacter polypeptide. The allowed species anticipates the instantly claimed genus.

20. The rejection of claim 25, 37-40,42, 46 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-15 of U.S. Patent No. 6,585,975 is traversed on the grounds that Helicobacter pylori polypeptides are administered and not Salmonella vectors which express Helicobacter pylori polypeptides.

21. It is the position of the examiner that the polypeptide antigens of amended claim 25 are defined by dependent claim 42 to encompass a "vaccinal vector comprising a sequence encoding a peptide or polypeptide from Helicobacter pylori placed under the control of the elements necessary for its expression". Therefore, although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed method comprises the steps of mucosally administering (claim 1 and col. 7, lines 45-51) a Helicobacter pylori polypeptide antigen expressed by a Salmonella vector (all claims and col. 5, lines 21-45) and then parenterally administering a Helicobacter pylori polypeptide antigen with alum (all claims, specifically claims 7-8 and col. 5, lines 21-45, col. 7, lines 49-51 defined to be urease or urease subunit of Helicobacter pylori claim 3 and col. 10, line 5); the allowed species anticipates the instantly claimed invention as now claimed.

22. ***Maintained, Claim Rejections - 35 USC § 102***: The rejection of claim 5 under 35 U.S.C. 102(b) as being anticipated by Fulginiti et al (1995) is traversed on the grounds that Fulginiti et al does not show whether the induced immune response is effective against challenge.

23. While no challenge experimental data was disclosed in Fulginiti et al, Fulginiti et al carried out the instantly claimed methods step. Fulginiti et al utilized an aroA mutant strain of Salmonella to express Helicobacter pylori urease. Meyer et al (EP 0835928 (see abstract)) provides evidence that the administered composition of Fulginiti would induce a protective immune response, because Meyer et al also produced and administered an aroA mutant strain of Salmonella (see page 17, claims 1-4) that expresses Helicobacter urease and the strain(s) are described by Meyer et al as inducing a protective immune response (mucosal) . Additionally, Chen et al (1993) provides evidence that the Fulginiti et al composition would induce a protective immune response based upon "intraperitoneal" administration of a Helicobacter antigen, because Chen et al administered Helicobacter antigen intraperitonelly, and found 55% protection upon challenge . Therefore Fulginiti et al inherently discloses the instantly claimed method.

24. ***Maintained***, The rejection of claims 5-6 under 35 U.S.C. 102(e) as being anticipated by Michetti et al (US Pat. 6,290,962; filing date February 23, 1994) in light of evidence provided by Guy et al (1997) is traversed on the grounds that Michetti et al administered a Helicobacter composition by rectal mucosal administration and the instant claims require subdiaphragmatic systemic routes of administration.

25. It is the position of the examiner that rectal administration is subdiaphragmatic, and the type of immune response induced would include both systemic and mucosal immune response in light of the fact that Michetti et al found both serum and intestinal secretions of antibodies (see Figure 2 and Description of the Drawings) "FIG. 2 is a graphic representation of the results from Table 1 of tests for antibodies in serum (IgG) and intestinal secretion (IgA) in mice that were protected after immunization with urease." Michetti et al still inherently anticipate the instantly claimed invention as now claimed.

Conclusion

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell(acting SPE) can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp
October 22, 2007

MARK NAVARRO
PRIMARY EXAMINER